

FLU VACCINE AVAILABILITY ACT OF 2001

—————  
JULY 26, 2001.—Committed to the Committee of the Whole House on the State of  
the Union and ordered to be printed  
—————

Mr. TAUZIN, from the Committee on Energy and Commerce,  
submitted the following

R E P O R T

[To accompany H.R. 943]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 943) to amend the Public Health Service Act with respect to the availability of influenza vaccine through the program under section 317 of such Act, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

	Page
Amendment .....	1
Purpose and Summary .....	2
Background and Need for Legislation .....	2
Hearings .....	3
Committee Consideration .....	4
Committee Votes .....	4
Committee Oversight Findings .....	4
Statement of General Performance Goals and Objectives .....	4
New Budget Authority, Entitlement Authority, and Tax Expenditures .....	4
Committee Cost Estimate .....	4
Congressional Budget Office Estimate .....	4
Federal Mandates Statement .....	6
Advisory Committee Statement .....	6
Constitutional Authority Statement .....	6
Applicability to Legislative Branch .....	6
Section-by-Section Analysis of the Legislation .....	6
Changes in Existing Law Made by the Bill, as Reported .....	6

AMENDMENT

The amendment is as follows:  
Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Flu Vaccine Availability Act of 2001”.

**SEC. 2. AMENDMENT TO PUBLIC HEALTH SERVICE ACT REGARDING AVAILABILITY OF INFLUENZA VACCINE.**

Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended by adding at the end the following paragraph:

“(3)(A) For the purpose of carrying out activities relating to influenza vaccine under the immunization program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 and 2003. Such authorization is in addition to amounts available under paragraphs (1) and (2) for such purpose.

“(B) The authorization of appropriations established in subparagraph (A) is not effective for a fiscal year unless the total amount appropriated under paragraphs (1) and (2) for the fiscal year is not less than such total for fiscal year 2000.

“(C) The purposes for which amounts appropriated under subparagraph (A) are available to the Secretary include providing for improved State and local infrastructure for influenza immunizations under this subsection in accordance with the following:

“(i) Increasing influenza immunization rates in populations considered by the Secretary to be high risk for influenza-related complications and in their contacts.

“(ii) Recommending that health care providers actively target influenza vaccine available in September, October, and November to individuals at increased risk for influenza-related complications and to their contacts.

“(iii) Providing for the continued availability of influenza immunizations through December of such year, and for additional periods to the extent that influenza vaccine remains available.

“(iv) Encouraging States as appropriate to develop contingency plans (including plans for public and professional educational activities) for maximizing influenza immunizations for high-risk populations in the event of a delay or shortage of influenza vaccine.

“(D) The Secretary shall submit to the Committee on Energy and Commerce in the House of Representatives, and the Committee on Health, Education, Labor, and Pensions in the Senate, periodic reports Congress describing the activities of the Secretary under this subsection regarding influenza vaccine. The first such report shall be submitted not later than June 6, 2002, the second report shall be submitted not later than June 6, 2003, and subsequent reports shall be submitted biennially thereafter.”.

**PURPOSE AND SUMMARY**

The purpose of H.R. 943, the Flu Vaccine Availability Act of 2001, as amended, is to ensure that flu vaccines are received by the States, and distributed to qualifying health care providers for the immunization of children, adolescents, and adults in accordance with established guidelines of the immunization program. This legislation also expresses the sense of the House of Representatives that oversight hearings should be convened immediately to determine: (1) the course of action followed by distributors of influenza vaccine during this influenza season; (2) whether or not such distributors put profit ahead of the health and well-being of the American people; and (3) whether it is necessary to take additional measures to ensure the safe, adequate, and timely supply of influenza vaccines in the future.

**BACKGROUND AND NEED FOR LEGISLATION**

Epidemics of influenza typically occur during the winter months and, according to the most recent report of the Advisory Committee on Immunization Practices (ACIP), are responsible for approximately 20,000 deaths per year in the United States. Rates of infection are highest among children, but rates of serious illness and death are highest among people over age 65 and persons of any age

who have medical conditions that place them at increased risk for complications from influenza.

On July 14, 2000, the Centers for Disease Control reported a substantial delay in the supply of the influenza vaccine for the 2000–01 season and the possibility of a vaccine shortage. The optimal time to administer influenza vaccine is October through mid-November, but a substantial amount of the flu vaccine was distributed late in the season. At that time, much of the limited vaccine supply was diverted from physicians and hospitals to non-professional distributors who distributed the vaccine on a first-come, first-serve basis, regardless of risk, thereby depriving patients most in need from receiving the vaccine.

While a resolution of manufacturing problems and improved yields of the vaccine averted a serious crisis, recent studies have indicated that a similar crisis may arise during the 2001–02 influenza season. In the Centers for Disease Control's Morbidity and Mortality Weekly Report (MMWR) dated July 13, 2001, vaccine distribution for the 2001–02 influenza season suggest that 49.8 million doses will be available for delivery by the end of October 2001—approximately 26 million fewer doses of the vaccine than were available by the end of October 1999 (75.8 million doses). However, manufacturers also project distribution of 27.3 million doses in November and December, bringing the cumulative projected total to 77.1 million doses, which is greater than the 70.4 million doses distributed in 2000 and comparable with the 76.8 million doses distributed in 1999.

Because of the potential for another influenza vaccine delay, the ACIP has developed supplemental recommendations. The goals of the recommendations are (1) to prioritize and phase in using vaccine for the 2001–02 influenza season to ensure that persons at greatest risk for severe influenza and its complications and their health-care providers receive vaccine early in the influenza season, and (2) to increase overall protection of those at greatest risk for severe influenza and its complications.

Steps must be taken to ensure the safe, adequate, and timely supply of vaccines in the future. H.R. 943 will help ensure that such a shortage, were it to happen again, would be alleviated by proper planning by CDC, the States, and local administrators of the vaccines. The Flu Vaccine Availability Act of 2001 helps ensure that influenza vaccine shortages do not jeopardize the health of thousands of Americans in future flu seasons. The bill would authorize funding under the Public Health Service Act immunization program for the distribution of influenza vaccine to qualifying health care providers, including physicians. Enactment of this measure would help prevent a recurrence of the distribution problems that took place during the 2000–01 flu season.

#### HEARINGS

The Subcommittee on Health held a hearing on H.R. 943 on June 27, 2001. The witness testifying on the bill was William J. Hall, M.D., President, American College of Physicians—American Society of Internal Medicine.

## COMMITTEE CONSIDERATION

On Wednesday, July 11, 2001, the Subcommittee on Health met in open markup session and approved H.R. 943 for Full Committee consideration, as amended, by a voice vote, a quorum being present. On Wednesday, July 18, 2001, the Full Committee met in open markup session and ordered H.R. 943 favorably reported to the House, as amended, by a voice vote, a quorum being present.

## COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 943 reported. A motion by Mr. Tauzin to order H.R. 943 reported to the House, as amended, was agreed to by a voice vote.

## COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a legislative hearing and made findings that are reflected in this report.

## STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of H.R. 943 is to ensure the safe, adequate, and timely supply of the influenza vaccine to those who are at greatest risk of influenza and its complications.

## NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 943, the Flu Vaccine Availability Act of 2001, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

## COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, July 24, 2001.*

Hon. W.J. "BILLY" TAUZIN,  
*Chairman, Committee on Energy and Commerce,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed estimate of H.R. 943, the Flu Vaccine Availability Act of 2001, as ordered reported by the Committee on Energy and Commerce on July 18, 2001.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Jeanne De Sa.

Sincerely,

BARRY B. ANDERSON  
(For Dan L. Crippen, Director).

Enclosure.

*H.R. 943—Flu Vaccine Availability Act of 2001*

H.R. 943 would permit the Centers for Disease Control and Prevention (CDC) to conduct activities to enhance influenza vaccination efforts by state and local governments and would authorize the appropriation of such sums as necessary in fiscal years 2002 and 2003 for that purpose. Those activities would focus on increasing influenza vaccination rates among adults, particularly high-risk populations and health care workers. The bill also would provide for the continued availability of the vaccine, and encourage states to develop contingency plans in the event of a vaccine shortage. Because CDC is authorized to conduct those activities under current law, CBO estimates the bill would not have a significant budgetary effect.

Section 317 of the Public Health Service Act provides an indefinite authorization of such sums as necessary for CDC to provide grants to state and local governments for the immunization of children, adolescents, and adults against vaccine-preventable diseases. Some grant awards target the improvement of vaccine delivery systems; others assist grantees in conducting immunization programs and purchasing vaccines.

In fiscal year 2001, CDC awarded \$159 million in grants to states and local governments for the improvement of operations and infrastructure of vaccine programs, most of which support activities related to childhood vaccinations. Only a few of the grantees target more than 10 percent of their fiscal year 2001 grant funds toward adult immunization efforts. Under existing authority, CDC could provide grant funds for purposes outlined in the bill. CDC has also recently recommended that state and local governments develop contingency plans in the event of a vaccine shortage.

The legislation would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply. H.R. 943 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on the budgets of state, local, or tribal governments.

The CBO staff contact is Jeanne De Sa. This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

## FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

## ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

## CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

## APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

## SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

*Section 1. Short title*

This Act may be cited as the “Flu Vaccine Availability Act of 2001.”

*Section 2. Amendment to Public Health Service Act regarding availability of influenza vaccine*

Section 2 provides such funds as may be necessary for providing for improved State and local infrastructure for influenza immunizations in accordance with the following: (1) assuring a priority system is intact for serving high-risk populations, (2) increasing public awareness on the effectiveness of the influenza vaccine late in the flu season, and (3) encouraging States to develop contingency plans for maximizing influenza immunizations in the event of a delay or shortage of influenza vaccine. This section also stipulates that the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce in the House of Representatives and the Committee on Health, Education, Labor, and Pensions in the Senate, periodic reports describing the activities of the Secretary regarding influenza vaccine.

## CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

**SECTION 317 OF THE PUBLIC HEALTH SERVICE ACT**

**PROJECT GRANTS FOR PREVENTIVE HEALTH SERVICES**

SEC. 317. (a) \* \* \*

\* \* \* \* \*

(j)(1) \* \* \*

\* \* \* \* \*

(3)(A) *For the purpose of carrying out activities relating to influenza vaccine under the immunization program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 and 2003. Such authorization is in addition to amounts available under paragraphs (1) and (2) for such purpose.*

(B) *The authorization of appropriations established in subparagraph (A) is not effective for a fiscal year unless the total amount appropriated under paragraphs (1) and (2) for the fiscal year is not less than such total for fiscal year 2000.*

(C) *The purposes for which amounts appropriated under subparagraph (A) are available to the Secretary include providing for improved State and local infrastructure for influenza immunizations under this subsection in accordance with the following:*

(i) *Increasing influenza immunization rates in populations considered by the Secretary to be high risk for influenza-related complications and in their contacts.*

(ii) *Recommending that health care providers actively target influenza vaccine available in September, October, and November to individuals at increased risk for influenza-related complications and to their contacts.*

(iii) *Providing for the continued availability of influenza immunizations through December of such year, and for additional periods to the extent that influenza vaccine remains available.*

(iv) *Encouraging States as appropriate to develop contingency plans (including plans for public and professional educational activities) for maximizing influenza immunizations for high-risk populations in the event of a delay or shortage of influenza vaccine.*

(D) *The Secretary shall submit to the Committee on Energy and Commerce in the House of Representatives, and the Committee on Health, Education, Labor, and Pensions in the Senate, periodic reports Congress describing the activities of the Secretary under this subsection regarding influenza vaccine. The first such report shall be submitted not later than June 6, 2002, the second report shall be submitted not later than June 6, 2003, and subsequent reports shall be submitted biennially thereafter.*